## REMARKS

Claims 17, 18, 20-41, 45-50, 53, 54, 70, 84, 85 and 90 are pending in this application. The remaining claims have been withdrawn.

Reconsideration of Claims 17, 18, 20-41, 45-50, 53, 54, 70, 84, 85 and 90, rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement of the statute, is respectfully requested.

Each of these claims is directed to Applicant's method of objectively identifying batched products. The broadest of the claims pending in this application is Claim 17 which reads:

> "17. The method of objectively identifying batched products comprising the steps of analyzing a batched product for the concentration of a plurality of the naturally occurring stable isotopes of said product after batching in their anthropogenically unaltered concentrations, arranging said concentrations of said isotopes into a mathematical array, formulating said mathematical array into a readable form, assembling product information, indexing said product information and said readable form thereby forming an index, and maintaining said index and said product information."

> "45. A method of providing an objective identification of a batched product comprising the steps of analyzing a plurality of the naturally occurring stable isotopes of said batched product after batching in their anthropogenically unaltered concentrations, deriving empirical information from said analyzing step, and arranging said empirical information into a numerical array."

> "50. A method for identifying a composition comprising identifying a plurality of the naturally occurring stable isotopes of said composition, analyzing said composition for the concentrations of a plurality of the naturally occurring stable isotopes of said composition after batching in their anthropogenically unaltered concentrations, deriving empirical information from said analyzing step, arranging said empirical information into a numerical array and formulating said numerical array into a readable form."

> "70. A method of providing an objective identification of a batched product comprising the steps of analyzing a batched product after batching for the anthropogenically unaltered concentrations of a plurality of the naturally occurring stable isotopes of said batched product, arranging said concentrations of said isotopes into a mathematical array, formulating said mathematical array into a readable form, assembling product information with regard to said batched product, indexing said product information and said readable form to a description of said product thereby forming an index, and maintaining said index and said product information and said readable form."

None of the claims are presently rejected under 35 U.S.C. §102 or §103 in view of prior art. The only rejection of these claims upon prior art historically has been based upon the patent issued to Welle, which has now been withdrawn because the Examiner has indicated that Welle teaches a method of identifying products by isotopes which is anthropogenically altered with exogenous stable isotopes in higher-than-natural abundance concentrations. Applicant claims a method in which the batched products analyzed are anthropogenically *unaltered,* specifically in terms of spiking. However, the Examiner states, with reference to Applicant's specification on page 8, without reference to any time frame that Applicant's batched products are anthropogenically altered in view of the fact that Applicant's claims would allow alteration of the product prior to batching. Applicant's claims have been amended to expressly eliminate alteration "after batching."

In each of Applicant's Claims 17, 45, 50 and 70, the language "after batching in their anthropogenically unaltered concentrations" refers to and modifies the "naturally occurring stable isotopes of the batched product" language. The word "naturally" as used here does not refer to "as in Nature"; instead, it refers to "as observed." This commonly-used shorthand terminology of isotope geochemists refers to materials which are not exogenous or added, but are

simply part of the observed or ambient composition of materials. Thus, once a batched product is isotopically identified, there is no anthropogenically altering of the naturally occurring isotopes of the batched product in performing Applicant's method.

By way of background, preceding application of Applicant's method, the batched product may have undergone anthropogenically altering steps such as reactions, distillations, fractionations, etc., prior to the batching process. However, Applicant's method is totally unconcerned with the historic processing of the product that may have occurred prior to batching. Whatever processing of the product that occurred historically prior to batching and whether or not such processing would alter the occurrence of concentrations of the isotope ratios in the batched product i.e., whether thermodynamic alteration (other that Welle's exotic-ratio spiking) or any kinetic isotope effect is of no concern to Applicant. Thus, the language "analyzing batched product for the concentration of a plurality of naturally occurring stable isotopes of said product" relates to a plurality of stable isotopes occurring in the batched product after the process of batching without any reference to whatever may have occurred to the product prior to batching.

The batching process as disclosed in Applicant's specification is a mixing/ homogenization process which results in a homogenous product which is subsequently sampled and analyzed for isotope ratios. Applicant's batching process would never include distillation as the result of distillation would not be a homogenous sample of the product distilled, or include any process that would alter the isotope concentrations of the batched product or include any kinetic isotope effect as the isotope concentrations of the resulting sample would not be the same as the originally analyzed material.

Additionally, Applicant has used the term "naturally occurring stable isotopes," not to refer to those stable isotopes occurring in Nature, but to those stable isotopes occurring in "the batched product" as they are observed upon analysis after batching without any anthropogenically alteration. Thus, if one of the materials in which one or more of the isotope concentrations has been "spiked" in accordance with the Welle patent, is identified as a batched product to be identified by Applicant's method, those "spiked" isotopic concentrations which do not occur in Nature become "naturally occurring stable isotopes" as defined by Applicant and as that term is utilized in Applicant's claims. Again, Applicant's claims are each focused on a batched product to be identified and the isotope concentrations of that batched product -- not to anything that has occurred to the product prior to batching.

Because Applicant's batching process is a simple physical or thermodynamic process and not a molecular or kinetic or isotope-ratio-altering process, Applicant's batched products are anthropogenically-isotopically unaltered and remain anthropogenically unaltered throughout the performance of Applicant's method from the sampling of the original batched material to the completion of the isotopic analysis at the laboratory and subsequent analysis. By contrast, the products analyzed by Welle are spiked with exogenous isotopes (a thermodynamic process) after batching. Thus, they are anthropogenically isotopically altered.

Applicant's batching process may also include what has been termed as "natural labeling" amongst those skilled in the art. (See Jasper et al 2004 *J. Pharm. Biomed. Anal.* 35:21-30), in which two or more chemically-homogenous samples of a product of known isotopic compositions can be mixed in known proportions to generate a third batched product of known chemical-, but different isotopic concentration as rigorously defined by the laws of mass balance

and isotopic mass balance. This concept was never anticipated by Welle or taught or disclosed or suggested by Welle.

Thus, it is not surprising that the Examiner has read through the specification and was unable to find any discussion of an anthropogenically unaltered-isotope concentration method, as Applicant's method begins with a batched product and proceeds with the step of analyzing for the concentration of a plurality of the "naturally occurring" observed stable isotopes of that product in their anthropogenically unaltered isotopic concentrations. Since Applicant's method starts with a batched product that has a plurality of naturally occurring stable isotopes in their anthropogenically unaltered concentrations, Applicant believed that there *was* no reason for Applicant to discuss such batch products in the specification. However, as the Examiner pointed out, in Applicant's specification on page 8 and elsewhere, Applicant (i) has identified examples of batched products, i.e., pharmaceutical ingredients (API's), drug products which are always batch manufactured, the excipients of drug products and/or impurities of drug products using concentrations of naturally occurring stable isotopes and (ii) expands Applicant's invention from those pharmaceutical ingredients to include batched products throughout the chemical, petroleum, pharmaceutical, biomedical, environmental, paint, explosive, ammunition and combustible fuel industries.

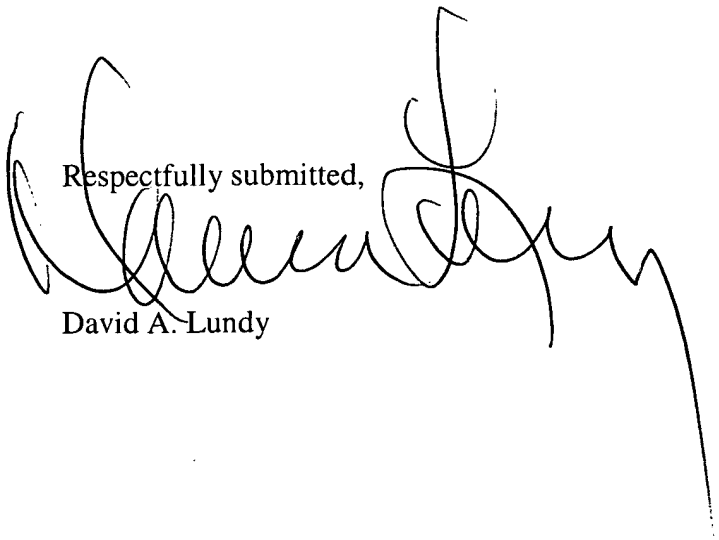
The discussion as to how products are batched has only arisen during the prosecution of Applicant's application because the Examiner has questioned what the terms "naturally occurring stable isotopes" or "naturally occurring stable isotopes in their unaltered condition" or "naturally occurring stable isotopes of said product in their anthropogenically unaltered concentrations" mean. Thus, there is no disclosure in Applicant's specification on page 8 or

elsewhere of the meaning of "batched product" as used in the specification as Applicant's method *starts* with a batched product, i.e., "The method of objectively identifying batched products * * *." As above stated, Applicant is wholly unconcerned with the process history of the batched product prior to batching, even whether the batched product has been processed by anthropogenically altering processes. Thus, it is not at all surprising that the Examiner has read through the specification and was unable to find any "anthropogenically unaltered isotope concentration method." What the Examiner found, however, was a "method of objectively identifying batched products" that does not include any anthropogenically isotope concentration altering processes after batching, and that fully supports all of the claims.

Finally, Applicant's specification cannot be objected to because Applicant has not disclosed how to arrive at a "batched product" as that procedure is well known to those skilled in the art to which Applicant's inventions pertain at the time the invention was made. Given the examples of batched products on page 8 of Applicant's specification, persons skilled in the art can easily identify batched products and describe how to arrive at a batched product, especially within the discussion of batched products which is now a part of the file history of this application. Applicant has no obligation to disclose in the specification "all batched products" or "all processes for arriving at a batched product" as that is where Applicant's method begins. The specification supports Applicant's claims with the disclosure of a single batched product.

For all of the reasons above given, Applicant respectfully submits that each of the claims, 17, 18, 20-41, 45-50, 53, 54, 70, 84, 85 and 90, as amended, are each in accordance with 35 U.S.C. §112, first paragraph. Applicant respectfully requests the prompt issuance of a Notice of Allowance.

Respectfully submitted,



David A. Lundy

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